

## **REMARKS**

Currently, claims 1, 3-13, 15-19, 21, 23 -28 are pending in the application. Claims 7 and 25-28 are withdrawn from consideration. Claims 23-24 are now canceled.

Claim 1 is amended to correct a typographical error and for clarity.

### **I. APPLICANTS' INVENTION**

The present invention relates to a removable device such as a stent-graft, intended for applications where it may be desirable to remove the device at some time following implantation. The stent-graft includes a helically-wound stent component provided with a covering of graft material having anisotropic strength properties. It is removable by gripping an end of the helically-wound stent component with a retrieval device and applying tension to the stent component in the direction in which it is intended to be withdrawn from the site of implantation. The use of such a retrieval device allows the stent-graft to be removed remotely, such as via a catheter inserted into the body at a different location from the implantation site. The design of the stent-graft is such that the stent component is extended axially while the adjacent portion of the graft separates between windings of the stent component. The axial extension of the stent component, with portions of the graft still joined to the stent component, allows the device to be "unraveled" (or "unwound") and removed through a catheter of diameter adequately small to be inserted into the body cavity that contained the stent-graft. It is removed atraumatically, without incurring significant trauma to the body conduit in which it had been deployed.

### **II. REJECTION OF CLAIMS 23 AND 24 UNDER 35 USC 112, FIRST PARAGRAPH AS FAILING TO COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT.**

Claims 23-24 are now canceled. These claims described means such as perforations intended to aid in splitting of the anisotropic ePTFE graft material. These means were fully contemplated by the inventors as a way of further weakening the anisotropic graft material. Applicants may choose to prosecute similar claims in a related application at a later date.

**III. REJECTION OF CLAIMS 1, 3-6, 8-13, 15-19 and 21 UNDER 35 USC 102(b) AS ANTICIPATED BY SMITH, US PATENT 6,364,904.**

The Examiner concludes that Smith teaches all of the elements of the 102(b)-rejected present claims. Smith teaches a stent-graft that is made from a helically wound strip of material (which may optionally be ePTFE) that is adhered to a length of serpentine, helically wound wire. For ePTFE, it is noted that that material can be made by uniaxial, biaxial or multiaxial stretching. While the uniaxial and biaxially stretched ePTFE materials can have anisotropic strength properties, any orientation of these materials with regard to the stent-graft assembly is not taught; indeed, none of these material choices is stated to be preferred.

At col. 2, lines 57-59, the Smith patent states that "It is still a further object of the present invention to provide a tubular stent/graft that has consistent wall properties without undesired seams, bumps or weak points." (Emphasis added.)

This very clearly constitutes a teaching away from the present invention.

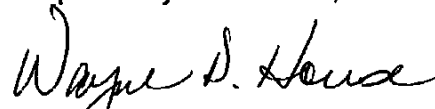
Further, Smith never teaches or suggests removability of his devices; the concept of removability is never addressed.

There is simply no suggestion to the person of ordinary skill that his devices might be splittable between adjacent stent elements by the use of an anisotropic graft material. Smith describes a stent-graft having consistent wall properties without weak points. Accordingly, the present claims are not anticipated by Smith.

## CONCLUSION

The applicants believe that their claims as amended are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance. If there remain any issues that might benefit from further discussion, the Examiner is requested to telephone the undersigned practitioner; likewise, the Applicants request an interview if such issues may remain.

Respectfully Submitted,



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